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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/582,152

06/08/2006

Richard Skiera

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BHATIA, AARTI

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/582,152	Applicant(s) SKIERA ET AL.	
	Examiner AARTI BHATIA	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 24-46 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 24-46 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7.28.2006</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

This is the initial Office Action based on the 10/582,152 application filed on 6/08/2006.

Claims 24-46 as amended on 6/08/2006, are currently pending and have been considered below.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 24, 26, 27, 30, 31, 32, 33, 34, 35, 36, 37, 38, 42, 43, 44, 45, and 46 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 4,959,054 to Heimke et al.

Heimke discloses the following:

24. An implant with an implant body (20), comprising an implant section (24) intended to remain in the body, a skin penetration section (24,36), and an extracorporeal connector section (96), and with a planar part (56) which surrounds the skin penetration section (24, 36), is provided for adhering to skin tissue and has a surface forming a support for a skin layer (28) surrounding the skin penetration section (24, 36), characterized in that the planar part (56) adjoins the skin penetration section (36) in a sterile manner and comprises, in one integral piece, an inner area adjoining the skin penetration section (24, 36), and an outer area (60), the inner area being made so

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stiff that it forms an inherently fixed support surface for a skin layer (28/32) surrounding the skin penetration section (24, 36), and the outer area (60) has an elasticity adapted to the elasticity of the surrounding tissue (column 8, lines 34-59).

26. The implant of claim 24, characterized in that the elasticity of the planar part (56) increases continuously toward the outside (column 8, lines 34-59).

27. The implant of claim 24, characterized in that the planar part (56) is made of silicone (column 7, line 25).

30. The implant of claim 24, characterized in that at least one surface of the plate-like part is provided with groove-like depressions or with webs (column 8, lines 34-59).

31. The implant of claim 24, characterized in that shaped elements promoting the anchoring of tissue are applied at least on one part of at least one surface of the planar part (see figures 4 and 5).

32. The implant of claim 24, characterized in that the surface of the planar part has, at least in some areas, a porous, net-like or roughened structure (see figure 5).

33. The implant of claim 24, characterized in that the surface is provided with substances that promote the adherence of tissue (see figure 6).

34. The implant of claim 24, characterized in that the planar part (36) has a substantially circular periphery (see figure 9).

35. The implant of claim 24, characterized in that the planar part (36) adjoins the implant body (24) substantially at right angles to a longitudinal axis of the implant body (see figure 9).

36. The implant of claim 24, characterized in that the planar part (56) is shaped like the top of a mushroom, with a jacket surface (60) forming an acute angle with respect to a longitudinal axis of the implant body (see figure 5).

37. The implant of claim 24, characterized in that the planar part is coated with bioactive material at least on one part of its surface (figure 11; column 7, lines 51-66).

38. The implant of claim 37, characterized in that the surface is coated in an island pattern with interstices (see figure 5).

42. The implant of claim 24, characterized in that the sterile connection is produced by a peripheral adhesive or weld filling the gap between the implant body (1) and the planar part (column 9, lines 9-14).

43. The implant of claim 24, characterized in that the implant body (20) is provided with a bioactive surface at least in the area of connection to the distal surface of the planar part (figure 11; column 7, lines 51-66).

44. The implant of claim 24, characterized in that the implant body is provided, in its connector section, with a surface that prevents microorganisms settling on it.

45. The implant of claim 24, characterized in that several implant bodies are connected to a common planar part (see figures 9 and 10).

46. The implant of claim 24, characterized in that, starting from an implant section, the implant body branches into several skin penetration sections which are connected to planar parts (see figures 9 and 10).

3. Claims 24, 28, 29, 39, 40, and 41 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 4,092,983 to Slivenko.

Slivenko discloses the following:

24. An implant with an implant body , comprising an implant section intended to remain in the body, a skin penetration section (19), and an extracorporeal connector section (65), and with a planar part (91, 99) which surrounds the skin penetration section (19), is provided for adhering to skin tissue and has a surface forming a support for a skin layer (97) surrounding the skin penetration section (19), characterized in that the planar part (91, 99) adjoins the skin penetration section (19) in a sterile manner and comprises, in one integral piece, an inner area adjoining the skin penetration section (19), and an outer area (99), the inner area (91) being made so stiff that it forms an inherently fixed support surface for a skin layer (97) surrounding the skin penetration section (19), and the outer area (99) has an elasticity adapted to the elasticity of the surrounding tissue.

28. The implant of claim 24, characterized in that the planar part is formed from several individual pieces (91,99).

29. The implant of claim 24, characterized in that the planar part (8) has a multiplicity of through-openings (101).

39. The implant of claim 24, characterized in that the planar part is connected releasably to the implant body (column 6, lines 58-68).

40. The implant of claim 24, characterized in that, in order to receive the planar part, the implant body has a stepped diameter reduction forming an annular shoulder (91; figure 1).

41. The implant of claim 40, characterized in that the sterile connection is produced by laying the planar part (99) flat on the annular shoulder (91) of the implant body with axial pretensioning (figures 1 and 5).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Heimke et al. or Slivenko in view of U.S. Patent No. 5,425,761 to Lundgren

Heimke and Slivenko both teach the implant of claim 24, but fail to teach that the implant is designed for attachment of a load, in particular of a prosthesis.

Lundgren teaches a subcutaneous implant with a through-passage which is adapted for both bone and tissue support (figure 3).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to adapt the implant of Heimke or Slivenko for attachment of a load, such as taught by Lundgren to combine bearing stability with good stability (column 1, lines 5-39).

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See PTO-892.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AARTI BHATIA whose telephone number is (571)270-5033. The examiner can normally be reached on Monday-Thursday 8:00am -6:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on (571) 272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Aarti Bhatia/
Examiner, Art Unit 3763

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763